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## Section III. 510(k) Summary

JUN 2 4 2013

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**Submitted by:**
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**Date of Submission:** 5 Dec 2012

**Proposed Device:** LawMax™ Dilator

**Classification:** Class II, DRE, 21 CFR 870.1310
Dilator, Vessel, For Percutaneous Catheterization

**Predicate Device:**

a) Edwards Lifesciences, LLC – RetroFlex™ Dilator Kit cleared under K093554
b) Estech – Estech Percutaneous Dilator Insertion Kit cleared under K070749

**Intended Use:** LawMax™ Dilator is is intended for use in the dilation of the peripheral vasculature.

**Device Description:** LawMax™ dilator is intended to dilate the puncture tunnel of the skin, subcutaneous tissue and vascular wall. The device is comprised of a dilator tube and a handle connected to its proximal end. There is a lumen in the tube center from distal end to proximal end which can accept a 0.038 inch guide wire. The tube surface is coated by hydrophilic coatings which can reduce the friction during the insertion manipulation. Operator can monitor the tube using fluoroscope guidance. A handle grip connected to the proximal end of the tube is available to facilitate operation. There is a hemostasis valve which can be adjusted to prevent blood leaking. The specification of LawMax™ dilator is definite by the outer diameter of the cylindrical part of the tube.

**Comparison with Predicate device:**
The LawMax™ Dilator is substantially equivalent to the predicate devices in intended use, design, specifications, packaging, and sterilization. For each predicate device there are slight variations, yet do not fundamentally change the scientific technology of the devices, which is to dilate vessels for introducing intravascular devices. A summary of equivalency is in Section 6.

**Testing Conclusion:** Performance testing was conducted to validate and verify that the proposed device met all design specifications and was substantially equivalent to the predicate device, including:

- Performance Test:
  - Primary Dimension Test
  - Exterior Surface Condition Test
  - Liquid Leakage Test
  - Bending Test
  - Solvent Resistance of Coating
  - Thickness of Coating
  - Simulating Test
  - Connection Strength (tube/handle)
  - X-Ray Visible
  - Conical Fitting Test
- Sterilization:
  - Sterilization Validation
  - Package Integrity
  - Endotoxicity Test
- Biocompatibility
  - Cytotoxicity Test
  - Sensitization Test
  - Intracutaneous Reacitivity Test
  - Acute Systemic Toxicity
  - Hemolysis Test
  - Thrombosis Test
  - Coagulation Test
  - Pryogen Test

**SE Conclusion:** Based upon the non-clinical testing noted above and in this 510(k) application, the LawMax™ Dilator meets the required standards and has demonstrated that it is as safe and effective as the predicate devices listed in this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 24, 2013

Lifetech Scientific (Shenzhen) Co., Ltd.
c/o Ms. Lily Shi
Regulatory Affairs Manager
Floor 1-3, Cybio Electronic Building
Langshan Second Street
Nanshan District
Shenzheng, Guangdong
China 518057

Re: K123842
Trade/Device Name: LawMax™ Dilator
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: II
Product Code: DRE
Dated: May 8, 2013
Received: May 23, 2013

Dear Ms. Shi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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## Section II. Indication for Use Statement

**510(k) Number:**

**Device Name: LawMax™ Dilator**

**Indication for Use:**

LawMax™ Dilator is intended for use in the dilation of the peripheral vasculature.

Prescription Use __X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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